Attorney Docket No.:6800-0010.04/ste

Client Reference: SHE 0010.13 Application No. 10/634,970

**PATENT** 

## In The Claims:

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1-67. Canceled

68. (Withdrawn) A method for preparing a purified polymer, said method comprising the steps of:

providing a water-soluble polymer comprising a site suitable for interacting with ion exchange chromatography media, and

purifying said polymer by ion exchange chromatography to obtain a purified polymer substantially absent polymeric impurities.

- 69. (Withdrawn) The method of claim 68, wherein said polymer is branched.
- 70. (Withdrawn) The method of claim 68, wherein said polymer is selected from the group consisting of poly(vinyl alcohols), poly(alkylene oxides), and poly(oxyethylated polyols), polyoxazoline, polyacroylmorpholine, polyvinylpyrolidone, and random or block copolymers and terpolymers thereof.
- 71. (Withdrawn) The method of claim 70, wherein said polymer is a poly(alkylene oxide).
- 72. (Withdrawn) The method of claim 71, wherein said polymer is a polyethylene glycol.
- 73. (Withdrawn) The method of claim 68 wherein said site suitable for interacting with ion exchange chromatography media is selected from the group consisting of carboxyl, hydroxyl, and amino.

74. (Withdrawn) The method of claim 72, wherein said polymer has a molecular weight ranging from about 100 to about 100,000 daltons.

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- 75. (Withdrawn) The method of claim 74, wherein said polymer has a molecular weight ranging from about 100 to about 50,000 daltons.
- 76 (Withdrawn) The method of claim 72, wherein said polymer comprises at least one end-capping group.
- 77. (Withdrawn) The method of claim 76, wherein said end-capping group is alkyl.
- 78. (Currently Amended) A method for preparing a purified polymer, said method comprising the steps of:

providing an impure polymer composition comprising

(i) a branched water-soluble polymer having the structure:

$$\begin{array}{c|c} PEG_{a} & & P \\ & & | \\ R & & C & Z \\ & & | \\ PEG_{b} & & Q \end{array}$$

where R is a non-reactive moiety, Z is a moiety comprising a site suitable for interacting with ion exchange chromatography media, PEG<sub>a</sub> and PEG<sub>b</sub> are each independently an end-capped polyethylene glycol (PEG), and P and Q each comprise a non-reactive linker absent an aromatic ring or ester group, and

(i) a polyethylene glycol (PEG) polymer, wherein said PEG polymer comprises an end capping group and a site suitable for interacting with ion exchange chromatography media,

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(ii) one or more polymeric impurities selected from the group consisting of PEG diol, end capped PEG-OH, and activated end-capped PEG, and

purifying said impure polymer composition by ion exchange chromatography under conditions effective to provide said <del>PEG</del> <u>branched water-soluble</u> polymer in substantially pure form.

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- 79. (Previously Presented) The method of claim 78, wherein said end-capping group is methyl and said polymeric impurities are selected from the group consisting of PEG diol, methoxy-PEG-OH, and activated methoxy-PEG.
- 80. (Currently Amended) The method of claim 78, wherein said PEG polymer is branched prior to said providing, said method comprises identifying said one or more polymeric impurities in said composition.
- 81. (Currently Amended) The method of claim 78, wherein said site suitable for interacting with ion exchange chromatography <u>media</u> is selected from the group consisting of carboxyl, hydroxyl, and amino.
- 82. (Currently Amended) The method of claim 81, wherein said site suitable for interacting with ion exchange chromatography <u>media</u> is carboxyl.
- 83. (Currently Amended) The method of claim 78, wherein said purifying further comprises:

loading the impure polymer composition onto an ion exchange chromatography medium to provide a loaded medium,

washing the polymeric impurities from said loaded medium using an aqueous eluent under conditions effective to elute said impurities from said medium,

adjusting the conditions of the aqueous eluent to effect elution of said <del>PEG</del> branched water-soluble polymer from the medium, and

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eluting said <u>PEG</u> <u>branched water-soluble</u> polymer from said medium to provide an aqueous solution comprising said <u>PEG</u> <u>branched water-soluble</u> polymer in substantially pure form.

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- 84. (Currently Amended) The method of claim 83, further comprising recovering said purified <u>branched water-soluble PEG</u> polymer from said aqueous solution.
- 85. (Currently Amended) The method of claim 83 78, wherein said PEG branched water soluble polymer is absent a hydrolytically unstable ester linkage has a molecular weight ranging from about 10,000 daltons to about 50,000 daltons.
- 86. (Previously Presented) The method of claim 83, wherein said end-capping group is methyl and said polymeric impurities are selected from the group consisting of PEG diol, methoxy-PEG-OH, and activated methoxy-PEG.
- 87. (Currently Amended) The method of claim 86, wherein said <u>branched water-soluble</u> polymer has a molecular weight ranging from about 100 to about 100,000 daltons.
- 88. (Currently Amended) The method of claim 86, wherein said PEG polymer further comprises a linker fragment connecting said PEG backbone to said site suitable for interacting with ion exchange chromatography media said activated end-capped PEG comprises an electrophilic activating group.
- 89. (Currently Amended) The method of claim 86 88, wherein said PEG polymer is absent an aromatic moiety said activated end-capped PEG comprises an active ester activating group.
- 90. (Previously Presented) The method of claim 86, wherein said adjusting step comprises adjusting the pH of the aqueous eluent.

91. (Previously Presented) The method of claim 86, wherein said adjusting step comprises adjusting the salt concentration of the eluent.

92. (Currently Amended) The method of claim 86, wherein said <u>branched</u> water-soluble polymer is branched has the structure:

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and mPEG<sub>a</sub> and mPEG<sub>b</sub> are each independently a monomethoxy polyethylene glycol.

- 93. (Currently Amended) The method of claim 92 78, wherein said polymeric impurities further comprise a mono-substituted PEG intermediate.
- 94. (Currently Amended) The method of claim 78 93, effective to essentially remove said polymeric impurities.
- 95. (Withdrawn) A polymer purified by the method of claim 68.
- 96. (Currently Amended) A PEG branched water-soluble polymer purified by the method of claim 78.

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- 97. (New) The method of claim 78, wherein P and Q are the same or different.
- 98. (New) The method of claim 78, wherein Z comprises a single site suitable for interacting with ion exchange chromatography media.
- 99. (New) The method of claim 92, wherein said polymeric impurities further comprise monomethoxy polyethylene glycol mono-substituted lysine.

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